

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ORTHO-McNEIL PHARMACEUTICAL INC., :
ORTH-McNEIL, INC., and :
DAIICHI SANKYO CO., LTD. :

Plaintiffs/Counterclaim-Defendants, :
v. :

LUPIN PHARMACEUTICALS, INC., and :
LUPIN LTD., :

Defendants/Counterclaim-Plaintiffs. :
:

Civ. No. 06-4999 (GEB)

MEMORANDUM OPINION

BROWN, C.J.

This matter comes before the Court upon the appeal of plaintiffs and counterclaim-defendants Orth-McNeil Pharmaceutical, Inc., Ortho-McNeil, Inc., and Daiichi Sankyo Company, Ltd.'s (collectively "Plaintiffs") of Magistrate Judge Bongiovanni's denial of Plaintiffs' motion to compel discovery. Plaintiffs seek an order: (1) overturning Magistrate Judge Bongiovanni's denial of Plaintiffs' motion to compel discovery from defendants and counterclaim-plaintiffs Lupin Pharmaceutical, Inc. and Lupin Ltd. (collectively "Lupin" or "Defendants"); and (ii) compelling Lupin to respond Plaintiffs' outstanding discovery requests. The Court has reviewed the parties' submissions and decided the motion without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth below, the Court will deny Plaintiffs' appeal.

I. BACKGROUND

Plaintiffs assert that this matter is a Hatch-Waxman pharmaceutical litigation. In July, 2006, Defendants submitted an Abbreviated New Drug Application ("ANDA") to the Food and

Drug Administration (“FDA”) seeking approval to commercially manufacture and sell generic levofloxacin. (Declaration of Robert A. Bourque (“Bourque Decl.”), Ex. A.) In Defendants’ ANDA, they certified, pursuant to Paragraph IV of the Hatch-Waxman act, that Defendants’ manufacture, marketing and sale of generic levofloxacin would not infringe any valid claim of Plaintiffs’ U.S. Patent No. 5,053,407 (the ‘407 patent”). (*Id.* at Ex. B; Plaint. Br. at 2.) Defendants notified Plaintiffs of their ANDA filing in a letter of September 29, 2008, after which Plaintiffs commenced this litigation, alleging that Lupin’s marketing and sale of generic levofloxacin would infringe the ‘407 patent. (*Id.*)

Defendants did not argue in their notice letter that the ‘407 patent was invalid and therefore unenforceable. Rather, Defendants asserted that the ‘407 patent was not eligible for the extension it was granted by the FDA and the Patent and Trademark Office (“PTO”) pursuant to 35 U.S.C. § 156, and therefore should have expired on its original expiration date in October 2008. (Plaint Br. at 4.) According to Defendants, the ‘407 patent was not eligible for extension because Plaintiffs’ marketing of levofloxacin was not the “first permitted commercial marketing or use” of the “product” or “active ingredient” in the product as defined by the statute. (*Id.*; Def. Br. at 3.); *see* 35 U.S.C. § 156(a)(5). Specifically, Defendants assert that the active ingredient in Levaquin (covered by the ‘407 patent) is (+) ofloxacin, which is an active ingredient in Floxin¹, a prior product approved by the FDA and commercially marketed in the U.S. (*Id.*) As such, Defendants assert that the extension for the ‘407 patent is invalid.

Because of Defendants’ theory in this case, the parties entered into a stipulation, stating

¹ Plaintiffs assert that Floxin contains ofloxacin, which is a racemic mixture (-) ofloxacin and (+) ofloxacin.

that the sole issue to be tried is limited to “whether the ‘407 patent is entitled to the term extension granted to it by the [USPTO] pursuant to 35 U.S.C. § 156.” (Borque Decl., Ex. C at ¶ 5.) Defendant further stipulated that it would not contest the validity of the ‘407 patent. (*Id.*)

Following the stipulation, Plaintiffs served Defendants with various discovery requests, which they maintain fall into one of three categories: (1) requests directed specifically to levofloxacin (the subject of Lupin’s ANDA, the compound claimed in the ‘407 patent and the active ingredient in Levaquin); (2) requests directed to ofloxacin (the racemic active ingredient in Floxin upon which Lupin relies in its Notice Letter); and (3) requests directed to Lupin’s current and past practices with respect to other enantiomers and racemates that it markets or has sought to market.” (Plaint. Br. at 5-6.) Defendants objected to the majority of Plaintiffs’ discovery requests. In light of this impasse, Magistrate Judge Bongiovanni instructed Defendants to produce a draft of its motion for summary judgment, with the accompanying expert report, to aid Plaintiffs in further gauging their need for discovery. (*Id.* at 8; Bourque Decl. at Exs. R, S.)

In Defendants’ draft summary motion papers, they argue that the ‘407 patent extension is invalid because it fails to satisfy 35 U.S.C. § 156(a)(5), which requires that the patent at issue be the “first permitted commercial marketing or use of the product” in order for an extension to be granted. Specifically, Defendants argue that the USPTO did not properly construe the terms “product” and “active ingredient” in the statute. Defendants assert that a proper construction of the statute, when applied to the undisputed facts, will demonstrate that the patent extension is invalid. (*Id.* at Ex. R, 9-10.)

Following Defendants’ filing of their draft summary judgement brief, Plaintiffs moved to compel discovery, which was opposed by Defendants. In denying Plaintiffs’ motion to compel,

Magistrate Judge Bongiovanni defined “the singular substantive issue underlying [the] motion [to be] whether the marketing of the patent in issue was or was not the first permitted commercial marketing or use of the active ingredient” in the patent. This issue, Judge Bongiovanni deemed to be one of statutory construction – “whether levofloxacin is an ‘active ingredient’ as defined by statute.” Magistrate Judge Bongiovanni further found that “the parties’ dispute is one of congressional intent, to wit, whether Congress intended the term ‘active ingredient’ to encompass the patent in issue.” As such, the court found that “the only type of information relevant would be, at most, evidence considered by the drafters in creating § 156 generally and § 156(2) specifically.” The court added that “the subjective nature of the information requested by Plaintiff cannot be considered relevant under the Court’s rules in determining whether either the plain language of the statute or the congressional intent behind its creation applies to the patent in issue.” To the extent Defendants sought to rely on evidence not possessed by Plaintiffs in the summary judgement motion, the court ordered that Defendants turn over said evidence prior to filing its motion. (Docket No. 48.)

II. DISCUSSION

A. Legal Standard

Local Civil Rule 72.1(c)(1)(A) and Federal Rule of Civil Procedure 72(a) provide that a Magistrate Judge's ruling on a non-dispositive motion will be set aside only if the order is "clearly erroneous or contrary to law." *See* L. CIV. R. 72.1(c)(1)(A); FED. R. CIV. P. 72(a). Such rulings are "entitled to great deference and [are] reversible only for abuse of discretion." *Kresefsky v. Panasonic Communs. & Sys. Co.*, 169 F.R.D. 54, 64 (D.N.J. 1996).

B. Whether Magistrate Judge Bongiovanni erred in denying Plaintiffs’ Motion to Compel

Discovery

Plaintiffs argue that Magistrate Judge Bongiovanni erred in denying their motion to compel discovery, as “the discovery sought by Plaintiffs is relevant to interpret the term ‘active ingredient.’” (Plaint. Br. at 10.) Plaintiffs further argue that the discovery it seeks is “relevant to several material issues of disputed fact related to ofloxacin, levofloxacin, racemates, and enantiomers that the Magistrate Judge mistakenly determined are irrelevant to this case as a matter of law.” (*Id.* at 14-18.)

By contrast, Defendants argue that because the only relevant issue in its draft summary judgment motion is one of statutory construction – whether the marketing of the ‘407 patent was the first permitted commercial marketing or use of its active ingredient, Plaintiffs’ discovery requests for information produced by Defendants after the enactment 35 U.S.C. § 156 should be denied. (Def. Br. at 5-9.) The Court agrees.

A court’s goal in interpreting a statute “is to give effect to Congress's intent.” *Rosenberg v. XM Ventures*, 274 F.3d 137, 141 (3d Cir. 2001). “Because it is presumed that Congress expresses its intent through the ordinary meaning of its language, every exercise of statutory interpretation begins with an examination of the plain language of the statute.” *Id.*; see also *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 476 (1992)(It is a “basic and unexceptional rule that courts must give effect to the clear meaning of statutes as written.”) “The plain meaning of legislation should be conclusive, except in the ‘rare cases [in which] the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters.” *United States v. Ron Pair Enters.*, 489 U.S. 235, 242 (U.S. 1989)(quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 571 (1982)). To make such a determination, courts

will often look to the legislative history of the act, to determine whether a contrary intent to the plain meaning of the statute exists. *Glaxo Operations UK, Ltd. v. Quigg*, 894 F.2d 392, 396 (Fed. Cir. 1990).

Plaintiffs cite *Corning Glass Works v. Brennan*, 417 U.S. 188 (U.S. 1974) and *Star-Glo Assocs., LP v. United States*, 414 F.3d 1349 (Fed. Cir. 2005) as supporting their argument that the discovery they seek is relevant to interpreting the term “active ingredient.” (Plaint. Br. at 10-14.) The Court is unpersuaded by Plaintiffs’ analogies to these cases. In *Corning Glass*, the United States Supreme Court was faced with the task of interpreting the term “working conditions” in the Equal Pay Act of 1963. 417 U.S. 188. In doing so, the Court paid close attention to the testimony of industry representatives (and indeed representatives from Corning) before Congress, which the Court concluded had caused Congress to amend the statute. *Id.* at 199-200. The Court observed that a Corning representative testified at one of the Congressional Hearings that “working conditions” consisted of two subfactors: “surroundings” and “hazards.” *Id.* at 202. The Court also found compelling that the amended statute defined the term “equal work,” by incorporating specific language, including the term “working conditions” directly from the testimony of one of Corning’s representatives at one of the Congressional Hearings. *Id.* at 200. The Court explained that because “Congress [] used technical words or terms of art, ‘it [was] proper to explain them by reference to the art of science to which they are appropriate.’” *Id.* at 201 (*quoting Greenleaf v. Goodrich*, 101 U.S. 278, 284 (1880)). The Court further emphasized that such an approach to statutory construction was appropriate where “the legislative history reveals that Congress incorporated words having a special meaning within the field regulated by the statute so as to overcome objections by industry representatives that

statutory definitions were vague and incomplete.” *Id.* at 202. In addition to noting that the definition of “working conditions” advocated by Corning was at odds with testimony of its own representative before Congress, the Court also observed that Corning’s job evaluation plans manifested a contrary definition of “working conditions” as did other evidence “across a wide range of American industry. *Id.* While the Supreme Court may have cited Corning’s job evaluation plans and other industry practice to buttress its interpretation of the relevant legislative intent and to demonstrate why Corning’s definition of “working conditions” was not credible, the Court’s interpretation of the Equal Pay Act was focused on the Act’s legislative history. *See id.* at 200. Nothing in the *Corning Glass* opinion suggests that an evaluation of Corning’s own business practices was required to determine the statutory meaning at issue.

The Court finds *Star-Glo* similarly unhelpful to Plaintiffs. The Federal Circuit examined a variety of evidence in *Star-Glo* to determine the meaning of the term “acre” in appropriations legislation enacted to compensate citrus farmers for citrus trees that had been eradicated. The court first noted that “[i]f the context and legislative history of the statute clearly indicate the congressional purpose” no further inquiry was necessary. 414 F.3d at 1356. Noting that the statute was “facially ambiguous,” the Circuit examined industry usage of the term through published data, definitions set forth by the state of Florida in addition to the United States Department of Agriculture, past practices of appellants and other growers, and the lack of opposition during the rulemaking process. However, the Circuit stressed that “[t]his is quite plainly an instance where the statutory term is a term of art that is defined most appropriately by the *preexisting* industry usage.” *Id.* (emphasis added). Thus, the court interpreted the statute based upon Congressional understanding of the term when the legislation was enacted.

Defendants assert that the term “active ingredient – had a well known meaning at the time of enactment of Section 156(f) and is not ambiguous.” (Def. Br. at 6.) To support this contention, Defendants will rely upon facts in their summary judgement motion that are all within the public records – namely “the composition of Floxin and Levoquin (the trademark for [Plaintiffs’] lovofoxacin product.” (Def. Br. at 8.) The Court need not address this contention, which is opposed Plaintiffs, for the purpose of this opinion. If Defendants can establish at summary judgement that the statutory language at issue is clear on its face, or when considered in light of the legislative history, than the Court need not inquire further in order to rule on the meaning of the term. If on the other hand, Plaintiffs are able to demonstrate that the statutory language is unclear – even after looking into the legislative history, and as a result, more discovery is required to determine the meaning of “active ingredient,” than Defendants’ summary judgement motion will fail. For the purpose of Defendants’ proposed summary judgment motion, no more discovery is required.

III. CONCLUSION

For the reasons set forth in this Memorandum Opinion, Plaintiffs’ appeal is denied. An appropriate form of order accompanies this Memorandum Opinion.

Dated: August 28, 2008

s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.